



April 10, 1985

Mr. John D. Maiers
Hansell and Post
56 Perimeter Center East, N.E.
Fifth Floor
Atlanta, Georgia 30346-2283

Dear Mr. Maiers:

This letter is in response to your application on behalf of Elekta Instruments, Incorporated, for registration of the Leksell Gamma System. A review of the application reveals that additional information is needed.

Please provide the following additional information:

- 1.) Manufacturer and model number of the sealed sources to be used in the Leksell Gamma System Model 23016;
- 2.) Measurements of scatter radiation from the Leksell Gamma System Model 23016 when the shielding door is open;
- 3.) A copy of the manufacturers radiological safety and operating instructions including start-up procedures, applicable to the Leksell Gamma System Model 23016, also, include recommended emergency procedures, maintenance and service schedules. Specify the maintenance to be performed by the customer and that which is to be performed by the manufacturer/distributor.
- 4.) A complete copy of the procedures for the removal of a patient in emergency situations.
- 5.) Describe how the Leksell Gamma System Model 23016 meets the design criteria in NCRP Report 33 Chapter 4.2.1. (d) 7.
- 6.) Describe all methods of closing the door of the Leksell Gamma System Model 23016;
- 7.) Describe how the collimator helmets are fixed to the couch of the Leksell Gamma System Model 23016;

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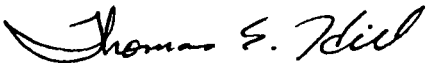
Additional Information for Registration of Leksell Gamma System

8.) Provide a facsimile of the control panel, including a description of all controls and indicators.

9.) What is the status for the approval for transportating the Leksell Gamma System Model 23016 when loaded with the 201 thirty curies cobalt 60 sources?

Should you have any questions, please do not hesitate to contact us.

Sincerely,



Thomas E. Hill, Chief
Radioactive Materials Unit
Radiological Health Section

TEH:dg